



— STATE OF SOUTH DAKOTA —  
**OFFICE OF THE GOVERNOR**  
KRISTI NOEM | GOVERNOR

July 12, 2023

The Honorable Robert M. Califf  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20903

Dear Commissioner Califf,

As Commissioner of the U.S. Food and Drug Administration, I know that you take the health of the American people quite seriously. But I also know that you are a parent yourself, and you would doubtless do whatever it takes to guarantee the best possible health opportunities for your own kids.

When my son, Booker, was growing up, he relied on the prescription drug Albuterol on an almost daily basis. Without it, he would not have been able to breathe. Imagine my shock when I recently learned that a widespread and long-lasting shortage of this critical drug has been impacting the United States of America. So many parents and their precious children have had to deal with the uncertainty of not knowing if that life-saving resource will be available to them.

Other drugs, like amoxicillin, have similarly been subject to these devastating shortages. A survey in February of this year found that [nearly 75% of all pharmacists](#) reported an ongoing amoxicillin shortage, the [most used antibiotic in the country](#).

As leaders, it is incumbent on us to take action to protect the health of our people.

Pharmaceutical drug shortages are not new. However, these shortages are occurring more frequently and lasting longer. The number of shortages is now hitting a critical point for healthcare practitioners and pharmacists who are unable to provide the recommended medication or treatment to give patients necessary care.

In December 2019, the Senate Committee on Homeland Security & Governmental Affairs [received a report](#) on the challenges health care providers and patients have faced in getting the medications they need due to lack of availability.

According to this report, over 80% of the active ingredients in prescription drugs sold throughout the United States now come from foreign countries, primarily China and India. This is a vulnerability for South Dakota and our nation because we are reliant on these countries for medications necessary to maintain the health of our citizens. This limited supply chain leaves the United States competing for the same resource as many other countries around the globe.

This is a global issue, and there are worldwide concerns about pharmaceutical reliance on China, a country who is our enemy.

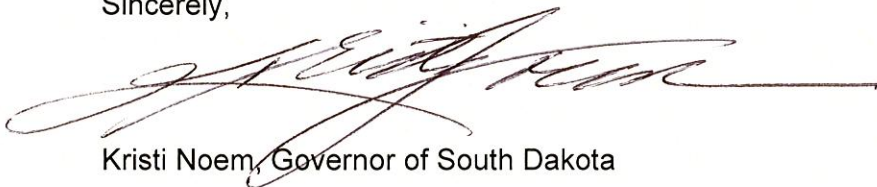
To date, little has been done to address this crisis. Here in South Dakota, we will take action to do what we can to address this crisis on our own. We will leverage and improve our existing pharmaceutical cache to stockpile critical medications.

We need Washington to take action. I implore you to work with Congress to deliver long-term policy solutions that demand:

- Transparency in the pharmaceutical manufacturing chain from sourcing raw materials to the finished product, including country of origin labeling;
- Increased diversity in the manufacturing of generic medications with regards to both raw materials and final manufacturing;
- Transparency from the FDA related to shortages and events that cause supply disruption;
- Extending useful life of medications when appropriate by re-examining FDA guidance related to expiration dates;
- Waivers to allow purchasing of medications from Canada to expand our supply chain capabilities quickly;
- Creation of a regulatory environment that is more favorable to U.S. manufacturing to include instituting shorter "cure periods" for U.S. manufacturing plants; and
- Requiring a risk assessment of foreign source active pharmaceutical ingredients.

These practical steps toward greater transparency and flexibility will ensure safety and dependability in our pharmaceutical supply chain. I look forward to your action in these areas. We stand ready to help here in South Dakota to advance these goals.

Sincerely,

A handwritten signature in dark ink, appearing to read "Kristi Noem", with a long, sweeping horizontal line extending to the right.

Kristi Noem, Governor of South Dakota